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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/765,624	01/26/2004	Michael Benser	A04P1008	2273
36802	7590	09/20/2007		
PACESETTER, INC. 15900 VALLEY VIEW COURT SYLMAR, CA 91392-9221			EXAMINER RIUTTA, ANDERS	
			ART UNIT	PAPER NUMBER
			3709	
			MAIL DATE	DELIVERY MODE
			09/20/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/765,624

Applicant(s)

BENSER ET AL.

Examiner

Anders Riutta

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3709

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) 12-17, 31, 32 and 34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-11, 18-30, 33 and 35 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date See Continuation Sheet.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- ☐ Notice of Informal Patent Application
- ☐ Other: ____.

Continuation of Attachment(s) 3. Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :01/26/2004, 05/10/2004, 08/25/2005.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-11, 19-30, 33, and 35, drawn to a method of or apparatus for diaphragm activation based on limit(s) on tidal volume, classified in class 607, subclass 42.
 - II. Claims 12-17, drawn to a method of diaphragm activation based on sensing either a crescendo or decrescendo in tidal volume, classified in class 600, subclass 538.
 - III. Claims 31, 32, and 34, drawn to a method of or apparatus for diaphragm activation based on airway patency, classified in class 600, subclass 533.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct if they do not overlap in scope and are not obvious variants, and if it is shown that at least one subcombination is separately usable. In the instant case, subcombination I has separate utility such as diaphragm activation without monitoring oscillations in tidal volume. See MPEP § 806.05(d).

The examiner has required restriction between subcombinations usable together. Where applicant elects a subcombination and claims thereto are subsequently found allowable, any claim(s) depending from or otherwise requiring all the limitations of the allowable subcombination will be examined for patentability in accordance with 37 CFR 1.104. See MPEP § 821.04(a). Applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the

present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

3. Inventions I and III are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct if they do not overlap in scope and are not obvious variants, and if it is shown that at least one subcombination is separately usable. In the instant case, subcombination I has separate utility such as diaphragm activation without monitoring airway patency. See MPEP § 806.05(d).

The examiner has required restriction between subcombinations usable together. Where applicant elects a subcombination and claims thereto are subsequently found allowable, any claim(s) depending from or otherwise requiring all the limitations of the allowable subcombination will be examined for patentability in accordance with 37 CFR 1.104. See MPEP § 821.04(a). Applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

4. Inventions II and III are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct if they do not overlap in scope and are not obvious variants, and if it is shown that at least one subcombination is separately usable. In the instant case, subcombination II has separate utility such as diaphragm activation without monitoring airway patency. See MPEP § 806.05(d).

The examiner has required restriction between subcombinations usable together. Where applicant elects a subcombination and claims thereto are subsequently found allowable, any

claim(s) depending from or otherwise requiring all the limitations of the allowable subcombination will be examined for patentability in accordance with 37 CFR 1.104. See MPEP § 821.04(a). Applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

5. Claim 18 link(s) inventions I and III. The restriction requirement between the linked inventions is **subject to** the nonallowance of the linking claim(s), claim 18. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions **shall** be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 **Claims that require all the limitations of an allowable linking claim** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, the allowable linking claim, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

6. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art in view of their different classification and due to their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

7. During a telephone conversation with Derrick Reed on August 7, 2007, a provisional election was made without traverse to prosecute the invention of Group I supra, claims 1-11, 19-30, 33, and 35 as well as linking claim 18. Affirmation of this election must be made by applicant in replying to this Office action. Claims 12-17, 31, 32, and 34 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Oath/Declaration

9. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

It does not state that the person making the oath or declaration acknowledges the duty to disclose to the Office all information known to the person to be material to patentability as defined in 37 CFR 1.56.

In particular, the correct statement should read, "I acknowledge the duty to disclose information which is material to **patentability** of this application in accordance with Title 37, Code of Federal Regulations Section 1.56." (Emphasis added).

Specification

10. The disclosure is objected to because of the following informalities:

- a. Paragraph 1: Please provide the application serial number for the related case.
- b. Paragraph 3: Missing "of" between "particular form" and "apnea."
- c. Paragraph 26: "provide" should be –provides-.
- d. Paragraph 68: "electrode" and "pole" should be –electrodes- and -poles-.
- e. Paragraph 94: Missing "of" between "characteristic" and "CSR."
- f. Paragraph 97: Spellings "hyponea" and "hypopnea" both used.

Appropriate correction is required.

Claim Objections

11. Claims 7, 21, and 30 are objected to because of the following informalities:

- g. Claims 7 and 21: "IEGM" should be written in non-abbreviated form.
- h. Claim 30: "delivery" should be –deliver-.

Appropriate correction is required.

Double Patenting

12. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined

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application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

13. Claims 1-9 and 19-30 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 and 20-31 of copending Application No. 10/765625. Independent claims 1 and 19 of the instant application differ from independent claims 1 and 20 of copending Application No. 10/765625 only in reciting a nondecreasing monotonic relationship instead of the nonincreasing monotonic relationship recited in copending Application No. 10/765625. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1 and 19 of the instant application are anticipated by claims 1 and 20, respectively, of copending Application No. 10/765625 since both an increasing and a decreasing monotonic relationship would anticipate a constant relationship and anticipation is the epitome of obviousness. Dependent claims 2-9 and 21-30 of the instant application are identical in substance to claims 2-9 and 22-31 (respectively) of copending Application No. 10/765625. Claim 19 of the instant application differs from claim 21 of copending Application No. 10/765625 in reciting "increasing tidal volume" instead of "decreasing difference between the tidal volume and the limit." Because tidal volume is recited

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as being less than the limit, increasing tidal volume is the same as decreasing difference between tidal volume and the limit.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

15. Claims 1-3, 6-9, 19-27, 30 are rejected under 35 U.S.C. 102(b) as being unpatentable over Scheiner (US 6,415,183). In claims 8 and 9, the "intends to..." clause has been carefully considered but deemed not to add further limitations to the claims, since increasing tidal volume is an intended outcome, rather than a recited step.

16. Regarding claims 1, 8, 9, and 19, Scheiner discloses the same invention substantially as claimed, including sensing minute ventilation (abstract), which is related to tidal volume (Col. 5,

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lines 47-48), a microprocessor determining if the tidal volume is less than a limit (Figure 2; Col. 6, lines 19-21), and calling for diaphragm activation (abstract; Col. 6, lines 19-21) with a constant stimulation power, a constant relationship being one form of a nondecreasing monotonic relationship (Col. 4, line 66 through Col. 5, line 1).

17. Regarding claim 2, Scheiner further discloses phrenic nerve stimulation (abstract).

18. Regarding claim 3, Scheiner further discloses delivering activation (abstract).

19. Regarding claims 6 and 22, Scheiner further discloses the limit relies on historical respiratory information unaffected by CSR (Col. 5, lines 44-62; Col. 6, lines 57-65).

20. Regarding claims 7 and 21, Scheiner further discloses impedance information (Col. 5, lines 44-63).

21. Regarding claim 20, Scheiner further discloses a connector (Figure 1A).

22. Regarding claim 23, Scheiner further discloses a pulse generator (Figure 1A, Element 170).

23. Regarding claim 24, Scheiner further discloses an output (Figure 1A and Figure 2, Element 225).

24. Regarding claim 25, Scheiner further discloses a connector (Figure 1A).

25. Regarding claims 26 and 27, Scheiner further discloses a pulse generator (Figure 1A, Element 170) and a lead (Figure 1A, Elements 120, 130, 140, and 150).

26. Regarding claim 30, Scheiner further discloses a cardiac stimulation output (Figure 1A; Col. 2, lines 10-27).

27. Claims 33 and 35 are rejected under 35 U.S.C. 102(e) as being anticipated by Tehrani (US 2005/0085865).

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28. Regarding claim 33, Tehrani discloses sensing respiratory information related to tidal volume (Paragraphs 11, 12; Paragraph 41, Line 6); determining if tidal volume is less than a limit (Figure 9C; Paragraphs 16, 71, 73); and calling for diaphragm activation at a stimulation power based on the tidal volume. (Paragraphs 18 and 71).

29. Regarding claim 35, Tehrani discloses sensing respiratory information related to tidal volume (Paragraphs 11, 12; Paragraph 41, Line 6); determining if tidal volume is less than a limit (Figure 9C; Paragraphs 16, 71, 73); and calling for diaphragm activation based on a nonincreasing monotonic relationship (Figure 9C; Paragraphs 71, 73). The nondecreasing monotonic relationship was not addressed because it was joined to the nonincreasing monotonic relationship by the word *or*, making the relationship in the alternative.

Claim Rejections - 35 USC § 103

30. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

31. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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32. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

33. Claims 5, 10, 11, 18, 28, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scheiner as applied to claims 1, 3, and 19 above, in view of Meer (US 4,830,008).

34. Regarding claim 5, Scheiner as applied to claim 3 is described above. Scheiner does not disclose monitoring upper airway patency. However, Meer teaches monitoring upper airway patency (abstract), in order to prevent upper airway collapse. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include the monitoring upper airway patency of Meer with the invention of Scheiner, in order to prevent upper airway collapse.

35. Regarding claims 10 and 11, Scheiner as applied to claim 1 is described above. Scheiner does not disclose monitoring upper airway patency. However, Meer teaches monitoring upper airway patency (abstract), in order to prevent upper airway collapse. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include the monitoring upper airway patency of Meer with the invention of Scheiner, in order to prevent upper airway collapse.

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36. Regarding claim 18, Scheiner discloses sensing minute ventilation (abstract), which is related to tidal volume (Col. 5, lines 47-48); determining if tidal volume is less than a limit (Figure 2; Col. 6, lines 19-21); and calling for diaphragm activation with a constant stimulation power, a constant relationship being one form of a nondecreasing monotonic relationship (Col. 4, line 66 through Col. 5, line 1). Scheiner does not disclose monitoring upper airway patency. However, Meer teaches monitoring upper airway patency (abstract), in order to prevent upper airway collapse. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include the monitoring upper airway patency of Meer with the invention of Scheiner, in order to prevent upper airway collapse.

37. Regarding claims 28 and 29, Scheiner as applied to claim 19 is described above. Scheiner does not disclose an input to receive information on upper airway patency. However, Meer teaches a monitor 14 for monitoring upper airway patency (Fig. 1 and Col. 4, lines 5-15), in order to prevent upper airway collapse (abstract). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include the monitor of Meer with the invention of Scheiner, in order to prevent upper airway collapse.

38. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Scheiner as applied to claim 3 above, in view of Ottenhoff (US 6,251,126). Regarding claim 4, Scheiner as applied to claim 3 is described above. Scheiner does not disclose delivering the activation during inspiration caused in part by intrinsic activity. However, Ottenhoff teaches delivering the activation during inspiration caused in part by intrinsic activity (Figure 5A; Figure 6, Elements 52 and 53; and Col. 2, lines 39-46). Therefore, it would have been obvious to one of ordinary

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skill in the art at the time the invention was made to include the synchronization of Ottenhoff with the invention of Scheiner, in order to treat dyspnea.

Conclusion

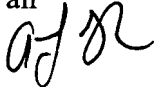
39. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Cho (US 2004/0138719), Hansen (US 6,357,438), and Park (US 6,881,192) all show innovation in the general state of the art of the invention.

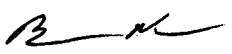
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anders Riutta whose telephone number is (571) 270-3514. The examiner can normally be reached on Monday through Thursday, 9:00AM to 4:00PM EDT.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terrence Till can be reached on (571) 272-1280. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

alr



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9/13/07
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